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PATENT COOPERATION TREATY

PCT

NOTIFICATION OF ELECTION

(PCT Rule 61.2)

From the INTERNATIONAL BUREAU

To:

Commissioner
US Department of Commerce
United States Patent and Trademark
Office, PCT
2011 South Clark Place Room
CP2/5C24
Arlington, VA 22202
ETATS-UNIS D'AMERIQUE

in its capacity as elected Office

Date of mailing (day/month/year) 10 January 2001 (10.01.01)	
International application No. PCT/AU00/00456	Applicant's or agent's file reference PH:FP12781
International filing date (day/month/year) 15 May 2000 (15.05.00)	Priority date (day/month/year) 13 May 1999 (13.05.99)
Applicant DUNLOP, Colin	

1. The designated Office is hereby notified of its election made:

☒ in the demand filed with the International Preliminary Examining Authority on:
13 December 2000 (13.12.00)

☐ in a notice effecting later election filed with the International Bureau on:

2. The election ☒ was
☐ was not

made before the expiration of 19 months from the priority date or, where Rule 32 applies, within the time limit under Rule 32.2(b).

The International Bureau of WIPO 34, chemin des Colombettes 1211 Geneva 20, Switzerland	Authorized officer R. E. Stoffel
Facsimile No.: (41-22) 740.14.35	Telephone No.: (41-22) 338.83.38

PCT

REQUEST

The undersigned requests that the present international application be processed according to the Patent Cooperation Treaty.

For receiving Office use only

International Application No.

International Filing Date

Name of receiving Office and "PCT International Application"

Applicant's or agent's file reference
(if desired) (12 characters maximum) IJS:PH:FP12781

Box No. I TITLE OF INVENTION	
MOTION MONITORING APPARATUS	
Box No. II APPLICANT	
Name and address: (Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this Box is the applicant's State (that is, country) of residence if no State of residence is indicated below.)	
DUNLOP, Colin 132A Cressy Road East Ryde, New South Wales, 2113 Australia	
<input checked="" type="checkbox"/> This person is also inventor.	
Telephone No. (02) 9878 8877	
Facsimile No. (02) 9878 8465	
Teleprinter No.	
State (that is, country) of nationality: Australia	State (that is, country) of residence: Australia
This person is applicant for the purposes of: <input checked="" type="checkbox"/> all designated States <input type="checkbox"/> all designated States except the United States of America <input type="checkbox"/> the United States of America only <input type="checkbox"/> the States indicated in the Supplemental Box	
Box No. III FURTHER APPLICANT(S) AND/OR (FURTHER) INVENTOR(S)	
Name and address: (Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country. The country of the address indicated in this Box is the applicant's State (that is, country) of residence if no State of residence is indicated below.)	
This person is:	
<input type="checkbox"/> applicant only	
<input type="checkbox"/> applicant and inventor	
<input type="checkbox"/> inventor only (If this check-box is marked, do not fill in below.)	
State (that is, country) of nationality:	State (that is, country) of residence:
This person is applicant for the purposes of: <input type="checkbox"/> all designated States <input type="checkbox"/> all designated States except the United States of America <input type="checkbox"/> the United States of America only <input type="checkbox"/> the States indicated in the Supplemental Box	
<input type="checkbox"/> Further applicants and/or (further) inventors are indicated on a continuation sheet.	
Box No. IV AGENT OR COMMON REPRESENTATIVE; OR ADDRESS FOR CORRESPONDENCE	
The person identified below is hereby/has been appointed to act on behalf of the applicant(s) before the competent International Authorities as: <input checked="" type="checkbox"/> agent <input type="checkbox"/> common representative	
Name and address: (Family name followed by given name; for a legal entity, full official designation. The address must include postal code and name of country.)	
Griffith Hack GPO Box 4164 Sydney NSW 2001 Australia	
Telephone No. 61 2 9957 5944	
Facsimile No. 61 2 9957 6288	
Teleprinter No.	
<input type="checkbox"/> Address for correspondence: Mark this check-box where no agent or common representative is/has been appointed and the space above is used instead to indicate a special address to which correspondence should be sent.	

Sheet No. 3....

Box No. VI PRIORITY CLAIM <input type="checkbox"/> Further priority claims are indicated in the Supplemental Box.				
Filing date of earlier application (day/month/year)	Number of earlier application	Where earlier application is:		
		national application: country	regional application: regional Office	international application: receiving Office
item (1) 13 May 1999	PQ4916	Australia		
item (2)				
item (3)				

☒ The receiving Office is requested to prepare and transmit to the International Bureau a certified copy of the earlier application(s) (only if the earlier application was filed with the Office which for the purposes of the present international application is the receiving Office) identified above as item(s): 1

* Where the earlier application is an ARIPO application, it is mandatory to indicate in the Supplemental Box at least one country party to the Paris Convention for the Protection of Industrial Property for which that earlier application was filed (Rule 4.10(b)(ii)). See Supplemental Box.

Box No. VII INTERNATIONAL SEARCHING AUTHORITY			
Choice of International Searching Authority (ISA) <i>(if two or more International Searching Authorities are competent to carry out the international search, indicate the Authority chosen; the two-letter code may be used):</i>	Request to use results of earlier search; reference to that search (if an earlier search has been carried out by or requested from the International Searching Authority): <div style="display: flex; justify-content: space-between;"> Date (day/month/year) Number Country (or regional Office) </div>		
ISA /			

Box No. VIII CHECK LIST; LANGUAGE OF FILING	
This international application contains the following number of sheets: request : 03 description (excluding sequence listing part) : 20 claims : 05 abstract : 01 drawings : 05 sequence listing part of description : Total number of sheets : 34	This international application is accompanied by the item(s) marked below: 1. <input type="checkbox"/> fee calculation sheet 2. <input type="checkbox"/> separate signed power of attorney 3. <input type="checkbox"/> copy of general power of attorney; reference number, if any: 4. <input type="checkbox"/> statement explaining lack of signature 5. <input type="checkbox"/> priority document(s) identified in Box No. VI as item(s): 6. <input type="checkbox"/> translation of international application into (language): 7. <input type="checkbox"/> separate indications concerning deposited microorganism or other biological material 8. <input type="checkbox"/> nucleotide and/or amino acid sequence listing in computer readable form 9. <input type="checkbox"/> other (specify):
Figure of the drawings which should accompany the abstract: <u>1</u>	Language of filing of the international application: <u>English</u>

Box No. IX SIGNATURE OF APPLICANT OR AGENT	
<i>Next to each signature, indicate the name of the person signing and the capacity in which the person signs (if such capacity is not obvious from reading the request).</i>	
<div style="border-top: 1px solid black; width: 100%; margin-bottom: 5px;"></div> Timothy John Staley Registered Patent Attorney for and on behalf of Griffith Hack	

For receiving Office use only	
1. Date of actual receipt of the purported international application:	2. Drawings: <input type="checkbox"/> received: <input type="checkbox"/> not received:
3. Corrected date of actual receipt due to later but timely received papers or drawings completing the purported international application:	
4. Date of timely receipt of the required corrections under PCT Article 11(2):	
5. International Searching Authority (if two or more are competent): <u>ISA /</u>	6. <input type="checkbox"/> Transmittal of search copy delayed until search fee is paid.

For International Bureau use only	
Date of receipt of the record copy by the International Bureau:	

Sheet No. 2

Box No. V DESIGNATION OF STATES

The following designations are hereby made under Rule 4.9(a) (mark the applicable check-boxes; at least one must be marked):

Regional Patent

- ☒ AP ARIPO Patent: GH Ghana, GM Gambia, KE Kenya, LS Lesotho, MW Malawi, SD Sudan, SL Sierra Leone, SZ Swaziland, TZ United Republic of Tanzania, UG Uganda, ZW Zimbabwe, and any other State which is a Contracting State of the Harare Protocol and of the PCT
- ☒ EA Eurasian Patent: AM Armenia, AZ Azerbaijan, BY Belarus, KG Kyrgyzstan, KZ Kazakhstan, MD Republic of Moldova, RU Russian Federation, TJ Tajikistan, TM Turkmenistan, and any other State which is a Contracting State of the Eurasian Patent Convention and of the PCT
- ☒ EP European Patent: AT Austria, BE Belgium, CH and LI Switzerland and Liechtenstein, CY Cyprus, DE Germany, DK Denmark, ES Spain, FI Finland, FR France, GB United Kingdom, GR Greece, IE Ireland, IT Italy, LU Luxembourg, MC Monaco, NL Netherlands, PT Portugal, SE Sweden, and any other State which is a Contracting State of the European Patent Convention and of the PCT
- ☒ OA OAPI Patent: BF Burkina Faso, BJ Benin, CF Central African Republic, CG Congo, CI Côte d'Ivoire, CM Cameroon, GA Gabon, GN Guinea, GW Guinea-Bissau, ML Mali, MR Mauritania, NE Niger, SN Senegal, TD Chad, TG Togo, and any other State which is a member State of OAPI and a Contracting State of the PCT (if other kind of protection or treatment desired, specify on dotted line)

National Patent (if other kind of protection or treatment desired, specify on dotted line):

- | | |
|--|--|
| <input checked="" type="checkbox"/> AE United Arab Emirates | <input checked="" type="checkbox"/> LR Liberia |
| <input checked="" type="checkbox"/> AL Albania | <input checked="" type="checkbox"/> LS Lesotho |
| <input checked="" type="checkbox"/> AM Armenia | <input checked="" type="checkbox"/> LT Lithuania |
| <input checked="" type="checkbox"/> AT Austria | <input checked="" type="checkbox"/> LU Luxembourg |
| <input checked="" type="checkbox"/> AU Australia | <input checked="" type="checkbox"/> LV Latvia |
| <input checked="" type="checkbox"/> AZ Azerbaijan | <input checked="" type="checkbox"/> MA Morocco |
| <input checked="" type="checkbox"/> BA Bosnia and Herzegovina | <input checked="" type="checkbox"/> MD Republic of Moldova |
| <input checked="" type="checkbox"/> BB Barbados | <input checked="" type="checkbox"/> MG Madagascar |
| <input checked="" type="checkbox"/> BG Bulgaria | <input checked="" type="checkbox"/> MK The former Yugoslav Republic of Macedonia |
| <input checked="" type="checkbox"/> BR Brazil | <input checked="" type="checkbox"/> MN Mongolia |
| <input checked="" type="checkbox"/> BY Belarus | <input checked="" type="checkbox"/> MW Malawi |
| <input checked="" type="checkbox"/> CA Canada | <input checked="" type="checkbox"/> MX Mexico |
| <input checked="" type="checkbox"/> CH and LI Switzerland and Liechtenstein | <input checked="" type="checkbox"/> NO Norway |
| <input checked="" type="checkbox"/> CN China | <input checked="" type="checkbox"/> NZ New Zealand |
| <input checked="" type="checkbox"/> CR Costa Rica | <input checked="" type="checkbox"/> PL Poland |
| <input checked="" type="checkbox"/> CU Cuba | <input checked="" type="checkbox"/> PT Portugal |
| <input checked="" type="checkbox"/> CZ Czech Republic | <input checked="" type="checkbox"/> RO Romania |
| <input checked="" type="checkbox"/> DE Germany | <input checked="" type="checkbox"/> RU Russian Federation |
| <input checked="" type="checkbox"/> DK Denmark | <input checked="" type="checkbox"/> SD Sudan |
| <input checked="" type="checkbox"/> DM Dominica | <input checked="" type="checkbox"/> SE Sweden |
| <input checked="" type="checkbox"/> EE Estonia | <input checked="" type="checkbox"/> SG Singapore |
| <input checked="" type="checkbox"/> ES Spain | <input checked="" type="checkbox"/> SI Slovenia |
| <input checked="" type="checkbox"/> FI Finland | <input checked="" type="checkbox"/> SK Slovakia |
| <input checked="" type="checkbox"/> GB United Kingdom | <input checked="" type="checkbox"/> SL Sierra Leone |
| <input checked="" type="checkbox"/> GD Grenada | <input checked="" type="checkbox"/> TJ Tajikistan |
| <input checked="" type="checkbox"/> GE Georgia | <input checked="" type="checkbox"/> TM Turkmenistan |
| <input checked="" type="checkbox"/> GH Ghana | <input checked="" type="checkbox"/> TR Turkey |
| <input checked="" type="checkbox"/> GM Gambia | <input checked="" type="checkbox"/> TT Trinidad and Tobago |
| <input checked="" type="checkbox"/> HR Croatia | <input checked="" type="checkbox"/> TZ United Republic of Tanzania |
| <input checked="" type="checkbox"/> HU Hungary | <input checked="" type="checkbox"/> UA Ukraine |
| <input checked="" type="checkbox"/> ID Indonesia | <input checked="" type="checkbox"/> UG Uganda |
| <input checked="" type="checkbox"/> IL Israel | <input checked="" type="checkbox"/> US United States of America |
| <input checked="" type="checkbox"/> IN India | <input checked="" type="checkbox"/> UZ Uzbekistan |
| <input checked="" type="checkbox"/> IS Iceland | <input checked="" type="checkbox"/> VN Viet Nam |
| <input checked="" type="checkbox"/> JP Japan | <input checked="" type="checkbox"/> YU Yugoslavia |
| <input checked="" type="checkbox"/> KE Kenya | <input checked="" type="checkbox"/> ZA South Africa |
| <input checked="" type="checkbox"/> KG Kyrgyzstan | <input checked="" type="checkbox"/> ZW Zimbabwe |
| <input checked="" type="checkbox"/> KP Democratic People's Republic of Korea | |
| <input checked="" type="checkbox"/> KR Republic of Korea | |
| <input checked="" type="checkbox"/> KZ Kazakhstan | |
| <input checked="" type="checkbox"/> LC Saint Lucia | |
| <input checked="" type="checkbox"/> LK Sri Lanka | |

Check-boxes reserved for designating States which have become party to the PCT after issuance of this sheet:

- ☒ (AL) Algeria
- ☒ (AG) Antigua and Barbuda

Precautionary Designation Statement: In addition to the designations made above, the applicant also makes under Rule 4.9(b) all other designations which would be permitted under the PCT except any designation(s) indicated in the Supplemental Box as being excluded from the scope of this statement. The applicant declares that those additional designations are subject to confirmation and that any designation which is not confirmed before the expiration of 15 months from the priority date is to be regarded as withdrawn by the applicant at the expiration of that time limit. (Confirmation (including fees) must reach the receiving Office within the 15-month time limit.)

PATENT COOPERATION TREATY
PCT
INTERNATIONAL PRELIMINARY EXAMINATION REPORT
(PCT Article 36 and Rule 70)

Applicant's or agent's file reference TJS:MG:FP12781	FOR FURTHER ACTION See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416).	
International Application No. PCT/AU00/00456	International Filing Date (<i>day/month/year</i>) 15 May 2000	Priority Date (<i>day/month/year</i>) 13 May 1999
International Patent Classification (IPC) or national classification and IPC Int. Cl. ⁷ A61B 5/11		
Applicant DUNLOP, Colin		

1.	This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.																								
2.	<p>This REPORT consists of a total of 5 sheets, including this cover sheet.</p> <p><input type="checkbox"/> This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).</p> <p>These annexes consist of a total of sheet(s).</p>																								
3.	<p>This report contains indications relating to the following items:</p> <table> <tr> <td>I</td> <td><input checked="" type="checkbox"/></td> <td>Basis of the report</td> </tr> <tr> <td>II</td> <td><input type="checkbox"/></td> <td>Priority</td> </tr> <tr> <td>III</td> <td><input checked="" type="checkbox"/></td> <td>Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</td> </tr> <tr> <td>IV</td> <td><input type="checkbox"/></td> <td>Lack of unity of invention</td> </tr> <tr> <td>V</td> <td><input checked="" type="checkbox"/></td> <td>Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</td> </tr> <tr> <td>VI</td> <td><input type="checkbox"/></td> <td>Certain documents cited</td> </tr> <tr> <td>VII</td> <td><input type="checkbox"/></td> <td>Certain defects in the international application</td> </tr> <tr> <td>VIII</td> <td><input type="checkbox"/></td> <td>Certain observations on the international application</td> </tr> </table>	I	<input checked="" type="checkbox"/>	Basis of the report	II	<input type="checkbox"/>	Priority	III	<input checked="" type="checkbox"/>	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability	IV	<input type="checkbox"/>	Lack of unity of invention	V	<input checked="" type="checkbox"/>	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement	VI	<input type="checkbox"/>	Certain documents cited	VII	<input type="checkbox"/>	Certain defects in the international application	VIII	<input type="checkbox"/>	Certain observations on the international application
I	<input checked="" type="checkbox"/>	Basis of the report																							
II	<input type="checkbox"/>	Priority																							
III	<input checked="" type="checkbox"/>	Non-establishment of opinion with regard to novelty, inventive step and industrial applicability																							
IV	<input type="checkbox"/>	Lack of unity of invention																							
V	<input checked="" type="checkbox"/>	Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement																							
VI	<input type="checkbox"/>	Certain documents cited																							
VII	<input type="checkbox"/>	Certain defects in the international application																							
VIII	<input type="checkbox"/>	Certain observations on the international application																							

Date of submission of the demand 13 December 2000	Date of completion of the report 5 September 2001
Name and mailing address of the IPEA/AU AUSTRALIAN PATENT OFFICE PO BOX 200, WODEN ACT 2606, AUSTRALIA E-mail address: pct@ipaaustralia.gov.au Facsimile No. (02) 6285 3929	Authorized Officer GEOFF SADLIER Telephone No. (02) 6283 2114

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/AU00/00456

I. Basis of the report

1. With regard to the elements of the international application:*

- ☒ the international application as originally filed.
- ☐ the description, pages , as originally filed,
 pages , filed with the demand,
 pages , received on with the letter of
- ☐ the claims, pages , as originally filed,
 pages , as amended (together with any statement) under Article 19,
 pages , filed with the demand,
 pages , received on with the letter of
- ☐ the drawings, pages , as originally filed,
 pages , filed with the demand,
 pages , received on with the letter of
- ☐ the sequence listing part of the description:
 pages , as originally filed
 pages , filed with the demand
 pages , received on with the letter of

2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language which is:

- ☐ the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of the translation furnished for the purposes of international preliminary examination (under Rules 55.2 and/or 55.3).

3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished

4. ☐ The amendments have resulted in the cancellation of:

- ☐ the description, pages
- ☐ the claims, Nos.
- ☐ the drawings, sheets/fig.

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).**

* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).

** Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/AU00/00456

III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be nonobvious), or to be industrially applicable have not been examined in respect of:

☐ the entire international application,

☒ claims Nos: 44-46

because:

☐ the said international application, or the said claims Nos. relate to the following subject matter which does not require an international preliminary examination (*specify*):

☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. are so unclear that no meaningful opinion could be formed (*specify*):

☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

☒ no international search report has been established for said claim Nos. 44-46

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

☐ the written form has not been furnished or does not comply with the standard.

☐ the computer readable form has not been furnished or does not comply with the standard.

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/AU00/00456

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Claims 1-30	YES
	Claims 31-43	NO
Inventive step (IS)	Claims 4-10, 19-25	YES
	Claims 1-3, 11-18, 26-43	NO
Industrial applicability (IA)	Claims 1-43	YES
	Claims	NO

2. Citations and explanations (Rule 70.7)

The following documents identified in the International Search Report have been considered for the purposes of this report:

D1 - US 5195531
D2 - EP 702978
D3 - US 4836219
D4 - US 5280791

Novelty (N) Claims 31-43

The claimed invention relates to an apparatus and method of monitoring animals and human patients under medical care and is intended to avoid problems which can occur if it is not realised that a patient is becoming aroused after anaesthesia or during critical care.

The solution according to the independent claims 1, 16, 31 and 37 comprises using a sensor to detect motion and then determining whether the motion is indicative of patient arousal.

Document D1 discloses an anaesthesia adequacy monitor which measures the level of consciousness of a patient (see column 7, lines 19-40) using a sensor array(20) to detect micro-expressions on the patients face.

Independent claims 1 and 16 differ from D1 by the inclusion of an alarm, however all the features of independent claims 31 and 37 are disclosed by D1 as is the additional feature of determining whether the patient is displaying signs of painfulness as defined in claim 36.

Document D2 discloses an apparatus for treating obstructive sleep apnea (see column 16, line 51 - column 17, line 28) which involves a respiratory waveform analysis that can be used to detect arousal of the patient via analysis of cough and body movement artefacts. D2 also contemplates the use of an activity sensor to determine arousal of the patient.

Independent claims 1 and 16 differ from D2 by the inclusion of an alarm, however all the features of independent claims 31 and 37 are disclosed by D2 as is the additional features found in claims 32-35, 37-40 and 42-43.

Continued on supplemental sheet.

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.

PCT/AU00/00456

Supplemental B x

(To be used when the space in any of the preceding boxes is not sufficient)

Continuation of Box V.

Document D3 discloses an electronic sleep monitor (see column 4, line 18 - column 5, line 26) which senses movement of the eyelid and head in order to determine the state of wakefulness of a patient.

Independent claims 1 and 16 differ from D3 by the inclusion of an alarm, however all the features of independent claims 31 and 37 are disclosed by D3 as is the additional features found in claims 38-39.

Document D4 discloses a system for determining the sleep state of a patient (see column 2, line 21 - column 3, line 19) and includes the use of ECG electrodes combined with a miniature body movement sensor attached to the chest, the combination of signals provided by these devices is then used to categorise the state of sleep.

Independent claims 1 and 16 differ from D4 by the inclusion of an alarm, however all the features of independent claims 31 and 37 are disclosed by D4.

Consequently the subject matter of claims 31-43 is not new and these claims fail to meet the requirements of Article 33(2) PCT with regard to the requirement for novelty.

Inventive Step (IS) claims 1-3, 11-18, 26-43

Claims 31-43: - as above

Independent claims 1 and 16 are distinguished from the cited art by the provision of an alarm which is indicative of patient arousal. However the use of alarm systems in medical monitoring devices of the type generally described by D1 - D4 is extremely well known and widespread. Consequently a person skilled in the art would be expected to incorporate an alarm into the apparatus of D1-D4 without difficulty, by routine steps so as to arrive at a solution which is the same as that of claims 1 and 16, therefore these claims lack an inventive step.

The additional features found in appended claims 2-3, 11-15, 17-18 and 26-30 can be readily observed in the documents D1-D4 and therefore these claims lack an inventive step for the reasons given above.

Claims 4-10 and 19-25 relate to additional features which are not disclosed by D1 -D4 and would not be obvious in the light of any of the cited documents nor are disclosed in any obvious combination, nor would they be obvious to a person skilled in the art in the light of common general knowledge by itself or in combination with any of these documents.

INTERNATIONAL SEARCH REPORT

International application No.

PCT/AU00/00456

A. CLASSIFICATION OF SUBJECT MATTERInt. Cl. ⁷: A61B 5/11

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC: A61B 5/-, A61D-

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

WPAT + Keywords

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5195531 A (BENNET) 23 March 1993 figure 2 and column 7, lines 19-40	1, 2, 11-13, 16, 17, 26-28, 30, 31, 36-39, 41
X	EP 702978 A2 (MEDTRONIC, INC.) 27 March 1996 column 16, line 51 - column 17, line 28	1-3, 11, 13, 15, 16, 18, 26-29, 31-35, 37- 40, 42, 43
X	US 4836219 A (HOBSON et al.) 6 June 1989 figure 1 and column 4, line 18 - column 5, line 26	1, 2, 11, 13, 16, 17, 26, 28, 31, 37-39

☒ Further documents are listed in the continuation of Box C ☒ See patent family annex

* Special categories of cited documents:

"A" document defining the general state of the art which is not considered to be of particular relevance

"E" earlier application or patent but published on or after the international filing date

"I" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

"O" document referring to an oral disclosure, use, exhibition or other means

"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art

"&" document member of the same patent family

Date of the actual completion of the international search

17 July 2000

Date of mailing of the international search report

Name and mailing address of the ISA/AU

AUSTRALIAN PATENT OFFICE
PO BOX 200, WODEN ACT 2606, AUSTRALIA
E-mail address: pct@ipaaustralia.gov.au
Facsimile No. (02) 6285 3929

Authorized officer

GEOFF SADLIER
Telephone No : (02) 6283 2114

INTERNATIONAL SEARCH REPORT

International application No.

PCT/AU00/00456

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5280791 A (LAVIE) 25 January 1994 column 2, line 21 - column 3, line 19	1, 16, 31, 37

INTERNATIONAL SEARCH REPORT

Internati nal application No.

PCT/AU00/00456

Supplemental Box

(To be used when the space in any of Boxes I to VIII is not sufficient)

Continuation of Box No: II

The international application does not comply with the requirements of unity of invention because it does not relate to one invention or to a group of inventions so linked as to form a single general inventive concept. In coming to this conclusion the International Searching Authority has found that there are different inventions as follows:

1. Claims 1 to 43 are directed to a method of monitoring a patient under medical care. It is considered that using a sensor to detect motion and then determining whether that motion is indicative of patient arousal comprises a first "special technical feature".
2. Claims 44 to 46 are directed to a device for monitoring a patient under medical care. It is considered that using a sensor to detect temperature and then comparing the measurement with a predetermined threshold comprises a second "special technical feature".

The feature common to all of the claims is the monitoring of a patient under medical care using a sensor. However this common feature is generic in the art. Consequently the common feature does not constitute "a special technical feature" within the meaning of PCT Rule 13.2, second sentence, since it makes no contribution over the prior art. Since there exists no other common feature which can be considered as a special technical feature within the meaning of PCT Rule 13.2, second sentence, no technical relationship within the meaning of PCT Rule 13 between the different inventions can be seen. Consequently it appears that a posteriori, the claims do not satisfy the requirement of unity of invention.

INTERNATIONAL SEARCH REPORT
Information on patent family membersInternational application No.
PCT/AU00/00456

This Annex lists the known "A" publication level patent family members relating to the patent documents cited in the above-mentioned international search report. The Australian Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

Patent Document Cited in Search Report			Patent Family Member		
US	5195531	NONE			
EP	702978	JP	8224317	US	5522862
US	4836219	NONE			
US	5280791	IL	100080		
					END OF ANNEX



INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

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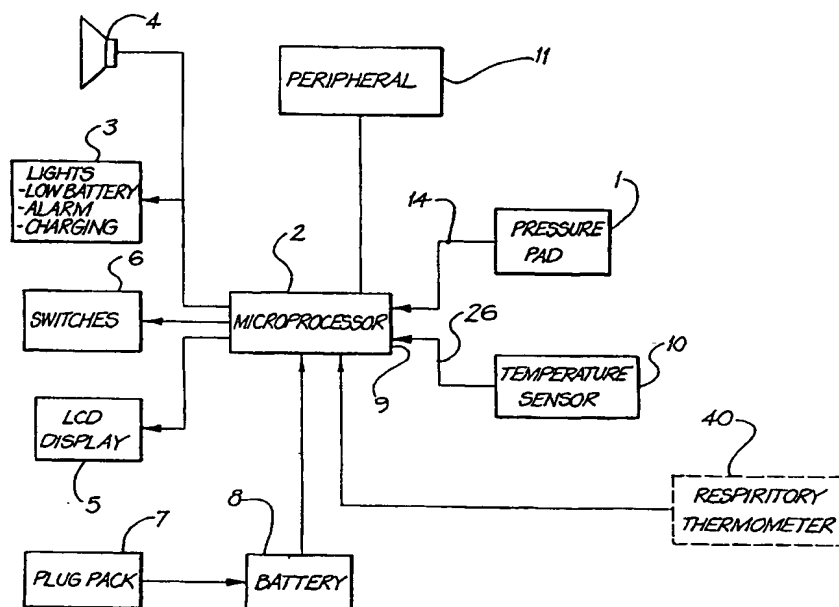
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With international search report.

(54) Title: MOTION MONITORING APPARATUS



(57) Abstract

The present invention relates to a motion monitoring apparatus and method for monitoring a patient under medical care. A sensor arrangement is provided in the form of a pad which the patient lies on. The sensor arrangement provides a signal which can be monitored to observe motion of the patient and provide an alarm should the motion meet certain predetermined conditions. The invention is particularly applicable for monitoring patients under sedation, recovering from anaesthesia, or in intensive care. The device is particularly useful for veterinary patients.

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MOTION MONITORING APPARATUSField of Invention

The present invention relates to an apparatus and
5 method of monitoring animals or human patients under
medical care.

Particularly, but not exclusively, the invention
relates to an apparatus and method of monitoring patients
who may be unconscious or semiconscious, undergoing medical
10 procedures or having undergone medical procedures, and
recovering from medical procedures, such as anaesthesia and
sedation, or during intensive care or critical care.

The apparatus and method is particularly applicable
to animal patient care, and the following description of
15 the invention will be given with reference to an animal as
a patient. The apparatus and method can be adapted for
human patient care, however.

Background of Invention

20 In veterinary practice, animals require heavy
sedation or general anaesthesia for any number of
procedures where sedation or anaesthesia would not
necessarily be required for a human patient. Note that in
the following description and claims when "anaesthesia" is
25 referred to it will be understood that "sedation" will also
be covered, and vice versa. Generally, animals require
sedation or anaesthesia to facilitate manipulative
procedures (e.g. radiographs), for minor surgical
procedures (e.g. dental procedures) and for major surgery
30 (e.g. ovariohysterectomy, fracture repair, etc.). In fact
anaesthesia is required for about one third of "income
generation" procedures. In busy practices this results in
many animals recovering from anaesthesia each day,
frequently with several animals recovering from anaesthesia
35 at the same time. Because of economic and manpower needs,
animals recovering from anaesthesia are not usually under
continuous observation by a trained person. Frequently

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these animals recover in large recovery or treatment rooms where other procedures are occurring. Therefore the veterinary staff "keep an eye" on the animals recovering from anaesthesia whilst their attention is otherwise
5 diverted.

The objective of monitoring a patient recovering from anaesthesia is to detect changes such as:

shivering
increasing chest excursions (rate or volume)
10 random body limb and neck movements
chewing, especially if the patient is intubated.

All the above changes reflect increased muscle tone associated with increasing activity and awareness of the nervous system as patients recover from the "relaxed" state
15 of general anaesthesia. Problems can occur if it is not realised that a patient is becoming aroused after anaesthesia or during critical care.

For example animals recovering from anaesthesia frequently remain intubated (a tube passing through the
20 mouth into the larynx and trachea, used to maintain an open airway) until their laryngeal function returns, such as when they swallow or cough. If intubated patients become conscious with the tube in place they usually become startled and start to chew the tube and to struggle. If
25 they are not attended to and the tube removed, it can be "bitten off" with part of the tube remaining in the trachea.

Further, veterinarians need to know if the patient develops an airway obstruction. Whether intubated or not,
30 semi-conscious animals (recovering from anaesthesia or during critical care) are at risk of developing airway obstructions which can result in hypoxia and death. This occurs because either an intubated patient may close its mouth/jaws on the endo-tracheal tube or a non intubated
35 patient moves about and can collapse with it's head twisted in a position where the airway becomes obstructed.

In addition to monitoring state of consciousness in

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animals recovering from anaesthesia veterinarians need to know that the patients temperature is returning to normal. Small animals such as cats and dogs have a relatively high surface area to body weight ratio and anaesthesia reduces muscle movement and shivering. Consequently hypothermia is the most common and potentially critical complication occurring during anaesthesia in small animals and during critical care of small semi-conscious patients. It is difficult to increase body temperature in patients that are already covered by sterile drapes for surgery particularly where a surgical procedure results in exposure of internal organs and cavities. Therefore once patients are placed in the recovery area their temperature is usually taken intermittently using a mercury or electronic thermometer and then efforts are made to increase their body temperature such as use of heating blankets, hot water bottles and heating lamps. Whilst the goal is to prevent further decrease in body temperature and to warm the patient, it is also possible to induce hyperthermia and occasionally severe skin burns if patients treated with heating devices are not adequately monitored. Accidents often happen where there are a lot of patients to observe. This may, for example, result in severe burns to a patient being warmed excessively, or, further, hypothermia can develop in the case of patients who have lost too much body heat and rewarming temperature monitoring has not been adequate. With the current methods, intermittent monitoring using mercury or electronic thermometers, this is more likely to happen.

All the above problems are compounded where there are a lot of patients being monitored simultaneously in a recovery or treatment room. It is very difficult to "keep an eye" on all the patients at the same time, and it may be the case that an animal becomes aroused without the veterinary staff being aware. These problems may occur, therefore, and often do in practising veterinary hospitals.

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Summary of Invention

From a first aspect, the present invention provides a method of monitoring a patient under medical care comprising the steps of providing a sensor arrangement which is arranged to detect motion of the patient, monitoring the motion of the patient by way of the sensor arrangement, determining whether the motion is indicative of patient arousal and providing an alarm should the motion be indicative of patient arousal.

10 Patient arousal may be indicated by bodily motion of the patient. As the patient becomes aroused they may start to "twitch" their limbs, for example. The present arrangement preferably detects that bodily motion and therefore indicates that the patient is becoming aroused.
15 By "bodily motion", note that we mean any motion of the patients body exclusive of motion of the chest wall due to respiration.

Preferably, the method of the present invention is applied for monitoring a patient during anaesthesia and recovery from anaesthesia, or during intensive care.

20 Preferably, in the method of the present invention an alarm is also provided when respiratory motion (motion of the chest wall and perhaps thoracic and of the body motion respiration, as opposed to bodily motion) of the patient increases, indicating that the patient is becoming aroused.

25 The alarm may be a visual alarm, audible alarm, a display or any other means for indicating that the motion is indicative of patient arousal.

Preferably the sensor arrangement includes a pad on which the patient lies, the pad mounting a sensor for monitoring motion of the patient. The pad may be of a similar construction to the arrangements used in SIDS (Sudden Infant Death Syndrome) monitors. Where the patient is an animal, in accordance with an embodiment of the present invention, the pad may be adapted for an animal to lie on. The pad preferably includes a piezo-electric sensor for detecting movement of the patient.

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Note that the objective of a SIDS monitor is to detect either chest or thoracic movement or ventilation by measuring expired CO₂, and to determine when respiration of a patient has slowed below a predetermined level or when
5 respiration has stopped (indicating apnoea).

In the case of the present invention, the sensor arrangement is preferably used to monitor for increased motion of the patient, indicative of the fact that the patient is becoming aroused i.e. their respiratory motion
10 is increasing to a more rapid state, or to monitor for bodily motion i.e., the patient is moving about (also indicative of arousal).

Preferably, in this aspect of the present invention, the motion of the patient is monitored by the following
15 method:

The sensor arrangement is arranged so that an output from the monitor occurs in accordance with movement. For example, when the patient breaths, and the chest moves, an output signal is produced. Further if the patient's body
20 moves (bodily motion as opposed to motion of the chest due to respiration), again a signal will be produced. The number of signals produced (note that by "signals" this includes variations in an otherwise constant signal which may be produced by the sensor arrangement i.e., one
25 variation equals an output signal) therefore varies according to the motion of the patient. When the patient is under sedation and breathing slowly and regularly, signals will be occurring at a regular rate. Signals from bodily motion will be imposed upon the regular rate
30 respiratory signals, and will appear as an increase in rate of the signals. Similarly, increase in respiration such as

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occurs when a patient is becoming aroused will cause an increase in rate of the signals. In accordance with the method of the present invention, if the signal rate increases beyond a predetermined threshold, it is
5 considered that either bodily motion is occurring or respiration is increased to such a rate implying arousal of the patient.

Preferably, a control means is provided and the method also includes the steps of setting a baseline level
10 for the signal rate of the sensor arrangement. The baseline level is preferably set by taking the signal rate when the patient is sedated or anaesthetised and using that signal rate as the baseline. The upper threshold is then set at a predetermined level above the baseline rate, for
15 example 20% above the baseline rate.

Note that motion of the patient may be monitored over time and any trends followed, to determine whether a patient is becoming aroused or not.
In an alternative embodiment, the sensor arrangement may
20 further include a conventional respiratory motion sensor, of the type presently used. These include such arrangements as a band which is passed around the patients chest and which includes an expansion spring. As the patients chest wall moves, the spring expands, varying the
25 resistance of an electrical circuit. An alternative conventional respiratory motion detector comprises a pair of electrodes placed on either side of the patients chest. When the electrodes move apart and together, in accordance with the chest motion of the patient due to respiration,
30 signals can be obtained indicative of the rate of respiration. Other detectors include respiratory thermometers, and end-expired carbon dioxide analysers, and others.

Signals from the respiration monitor can be compared
35 with signals from the sensor pad arrangement, to isolate the signals which are due to bodily motion. Bodily motion and motion due to respiration can therefore, in this embodiment, be monitored separately.

In a preferred embodiment of the present invention,
40 an alarm may also be provided when the sensor arrangement

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indicates that the patient's motion falls below a predetermined level, i.e. that there may be an apnoea situation or unconsciousness/death due to hypoxia caused by an airway obstruction. The major objective of the present invention, however, is to monitor for states of arousal, so that the patient can be attended to. An alarm (which may be visual or audible or both) is preferably arranged to indicate to an observer that it is time to attend to the patient and remove any tubes from their trachea and perform any other treatment which may be necessary.

Preferably, the temperature of the patient is also constantly monitored. In the prior art, temperature monitoring is intermittent, as discussed above. In the present invention, temperature is preferably monitored constantly, by use of a temperature monitor (which may be by temperature thermistor; rectal oesophagel or inter-digital probe placement) and an alarm is provided should the temperature fall outside predetermined ranges, preferably indicative of potential hypothermic or hyperthermic states.

Preferably a monitoring device includes control means for monitoring the signals from the sensor arrangement and temperature sensor (where one is utilised) and providing outputs on a visual display and also audibly. Preferably, the control means is mounted in a housing which is mountable to a housing (e.g., cage or cage door) containing the animal patient. The monitoring device is therefore associated with a particular animal patient and the visual alarm immediately attracts the attention of the operative to the correct patient.

The present invention further provides a device for monitoring a patient under medical care, comprising a sensor arrangement which is arranged to detect motion of the patient, and a control means which is arranged to process signals received from the sensor arrangement to determine whether the motion is indicative of patient arousal and to provide an alarm should the detected motion

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be indicative of patient arousal.

The device preferably further includes means for receiving signals from a temperature sensor and providing an alarm for output if the temperature falls outside a predetermined range, preferably indicative of potential hyperthermic or hypothermic states. Preferably, the device also provides an alarm when the motion drops below a predetermined level or ceases, indicative of a state of apnoea, as discussed above.

10 The control means is also preferably arranged to carry out any or all of the method steps discussed above.

The present invention further provides a system including a plurality of devices as discussed above, the sensor arrangements mounted with respect to housings containing animals, to monitor a plurality of animals under medical care.

20 The monitoring of motion of patients who are under intensive care or under critical care may also provide information additional to the state of consciousness of the patients. For example, when a conscious or semiconscious animal patient under care is in pain, bodily motion may either be absent or rhythmic and "jerky" (or could follow other patterns indicative of pain). Bodily motion can therefore be used as an indicator of level of pain in a patient.

Bodily motion can also be used to determine a number of other conditions e.g. to provide evidence of normal sleep/wake cycles, patients with history of syncope (e.g., heart disease, diabetes).

30 Such an analysis of motion of a patient may be particularly useful with animal patients and young human beings that cannot vocalise their condition.

From a further aspect, the present invention provides a method of monitoring a patient under medical care, comprising the steps of providing a sensor arrangement which is arranged to detect motion of the patient, monitoring the motion of the patient by way of the sensor

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arrangement, and analysing the motion of the patient to determine the medical condition of the patient.

The motion of the patient may be analysed to determine whether or not the medical condition is
5 indicative of pain. For example, rhythmic and jerky motion may be considered to be indicative of pain as, with a conscious patient, no movement may be indicative of pain.

Preferably, a trend analysis of the motion of the patient may be made. That is over a long term (hours and
10 days) the motion may be monitored to follow the trend of the patient e.g., the "painfulness" of the patient reducing over time, implying that they are responding to treatment. A trend analysis may provide an average rate of motion read out per day which a physician may use to track the
15 condition of the patient. Such an analysis would be particularly useful for critical care applications where patients are recovering from major surgery, e.g., spinal fracture in a dog. The analysis could measure acute (short term) motion changes as well as long term changes.

20 Preferably, the sensor arrangement includes a pad positioned under the patient, as for the first aspect of the invention discussed above.

Preferably, a control means is provided which provides an output indicative of the motion of the patient
25 over a period of time. The output may be graphical or the control means may also carry out a trend analysis and determine the condition of the patient. If the output is graphical, this can be delivered to a physician to enable the physician to track the medical condition of the
30 patient.

The present invention further provides a device for monitoring a patient under medical care, comprising a sensor arrangement which is arranged to detect motion of the patient, and a control means which is arranged to
35 process signals received from the sensor arrangement to analyse the motion of the patient, whereby to enable a determination of the medical condition of the patient.

- 10 -

The control means may provide a graphical output of the motion of the patient over a period of time, or may provide an output indicative of a condition of the patient determined by the control means.

5 The sensor arrangement preferably includes a pad monitor, as discussed above.

 With any of the aspects of the invention discussed above, preferably the output from the sensor arrangement may be used, via a control means, to control operation of a
10 peripheral device in response to a determined medical condition of the patient or in response to the patient becoming aroused from sedation or anaesthesia. For example, an output could be provided to control a heating device to turn on or off a heating pad, to control a
15 ventilator (e.g., a dog with tick paralysis), or to control a syringe pump turning on or off a flow of analgesic medication or treatment or therapy.

 The output from the sensor arrangement may be transmitted to a computer, for the computer to provide the
20 alarm or track and analyse the trend in the motion of the patient. The computer may be situated remotely (e.g. in another part of a hospital or even at the physician's place of residence) and the signals from the arrangement be transmitted to the computer at the remote location.

25 Preferably, when bodily motion is monitored, track is kept of the motion of all parts of the body and not just isolated parts of the body.

 Features and advantages of the present invention will become apparent from the following description of an
30 embodiment thereof, by way of example only, with reference to the accompanying drawings, in which:

 Figure 1 is a block diagram of components of a device in accordance with an embodiment of the present invention;

 Figure 2 is a schematic exploded diagram of a
35 pressure pad motion sensor of the device of Figure 1;

 Figure 3a is a perspective view of a device in accordance with an embodiment of the present invention;

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Figure 3b is a view of a front panel of a device of Figure 3a;

Figure 4a and figure 4b are schematic examples illustrating signals which may be output by the motion
5 sensor, and

Figure 5a and figure 5b are further schematic diagrams illustrating signals which may be output by an embodiment of the present invention for the purposes of determining a medical condition of a patient.

10 Referring to the drawings, a device is illustrated which can be used to detect motion of a patient who is recovering from anaesthesia or sedation, or is in critical or intensive care and may be in an unconscious or semi-conscious state. The illustrated device is particularly
15 designed for use with animals, in veterinary hospitals, for example, but may be adapted for use with human beings.

The device comprises a sensor arrangement which is arranged to detect motion of the patient, in this particular embodiment being a pressure pad sensor
20 arrangement 1, and a control means including a microprocessor 2 for monitoring the motion of the patient and determining whether the motion of the patient is indicative of the patient becoming aroused. Either bodily motion or increased respiratory motion of the patient may
25 indicate that the patient is becoming aroused. Preferably, bodily motion and respiratory motion of the patient are monitored by the control means. In this embodiment a visual alarm is provided by lights such as LEDs 3, and an audible alarm is provided by loudspeaker 4.

30 The device also includes an LCD display 5 for providing visual display information; an input means such as switches 6 for setting input parameters and otherwise controlling the device; a power supply including a plug pack 7 enabling connection to the mains and also a battery
35 8, which is preferably a rechargeable battery. The device also includes an input 9 for receiving data from a temperature sensor 10, which may, for example, be a

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temperature thermistor (rectal, oesophageal or inter-digital probe placement), whereby the device can constantly monitor the temperature of the patient.

The device may be connected to a peripheral unit 11, for the purposes of controlling the peripheral unit via the microprocessor 9 in accordance with signals from the pressure pad monitor 1. For example, the peripheral unit 11 may be a ventilator, controllable by the microprocessor 9 to increase or decrease oxygen to a patient's lungs. Alternatively, it may be a syringe pump for adjusting a flow of analgesic. It may be any other type of device which it may be desirable to control in order to facilitate the condition of the patient.

In more detail, referring to figure 2, an exploded view of a pressure pad, generally designated by reference numeral 1, is shown. Pressure pad 1 comprises a rigid base 12, which may be metal, for example. On top of the rigid base 12 a flexible membrane 13 is mounted (note that in practice the membrane will be directly on top of the rigid base 12). On the membrane a further rigid strip 13a is laminated. The strip 13a is connected to a Piezo-electric transducer 13b. When a change of pressure occurs on the strip 13a of Piezo-electric transducer 13b, a signal will be produced. If a patient lies on the pad 1, therefore, any movement of the patient will produce a signal, whether the movement is due to respiratory movement (movement of the chest) or bodily motion. Note that the entire arrangement would be covered in flexible material, which may be plastics, for example (not shown). Piezo-electric transducer 13 is electrically connected to cable 14 which is input to the microprocessor 9 (Figure 1). The pressure pad 1 may be similar to the type of pressure pad used in earlier versions of SIDS (Sudden Infant Death Syndrome) monitors. The application of the pressure pad 1 in this embodiment of the invention, however, is different from what SIDS pad monitors were designed to do. SIDS pad monitors were arranged to watch for the absence of

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respiration (apnoea). That is, when very low rate signals or no signals are being received, indicative of the fact that an infant may have stopped breathing or may have moved off the pad, then an alarm will be given. For the present
5 invention, however, the use of the pressure pad 1 and associated control means is also to watch for bodily motion, or increased respiratory activity, both of which are indicative of the patient becoming aroused.

With the device of the present invention, the
10 microprocessor 9 is programmed to watch for an increase in rate of signals produced by the transducer 13. Referring to figures 4a and 4b, figure 4a shows over a predetermined time period A the production of three signals by the transducer 13. These signals are regularly spaced from
15 each other and are indicative of, for example, a steady, slow respiration rate, indicating that the patient is unconscious.

In figure 4b, however, a further signal X has been produced within the time period A. Such a signal may be
20 due to bodily motion of the patient on the pad 1, indicating that the patient is becoming aroused. The microprocessor sees this extra signal or extra signals produced during the time period A as an increased rate. If this increased rate extends beyond a predetermined
25 threshold, then an alarm will be given.

The increase in rate may be due to bodily motion or due to an increase in respiratory rate, both indicative of patient arousal.

For different patients, the thresholds at which
30 alarms are given and the base respiration rate (base signal rate figure 4a) will vary. The device of the present invention is provided with a baseline set or "quick set" feature. When the baseline set function is actuated, the device samples the current motion (signals from transducer
35 13) which will usually be regular and slow when the patient is sedated or recovering from anaesthesia. This rate is determined to be the baseline rate. Thresholds of, for

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example, plus or minus 20% of the baseline rate is then automatically determined and if the signal should increase above the upper threshold or fall below the lower threshold, then an alarm will be given.

5 In operation, when an alarm is given, a operative will attend the patient and see if the patient is becoming aroused. If the patient is not becoming aroused, the baseline function may again be actuated, adjusting the baseline rate to the new rate of motion of a patient (which
10 may be a slightly higher rate of respiration, but still not sufficient to indicate arousal). The thresholds will then also be automatically adjusted.

 Note that, alternatively to the baseline set feature, the device also includes means for manually setting a
15 baseline and also threshold limits for the alarms. In a preferred embodiment, it also includes means for setting baselines depending upon type of patient, e.g., standard dog, standard cat, etc., and also threshold levels.

 The monitor is also programmed to watch for apnoea
20 (lower threshold level). That is, if motion rate drops below a predetermined level (indicative of apnoea), then the alarm will be given.

 Further, the monitor is arranged to monitor the temperature of the patient by way of the temperature sensor
25 10 and give alarms should the body temperature fall above or below predetermined thresholds. Again, these thresholds are adjustable by way of the switches 6 so that the veterinarian can vary the parameters depending upon the patient. The thresholds are set to avoid hypothermia or
30 hyperthermia in the patient. As well as manual setting of these parameters there may also be provided preset parameters for different animal varieties, as with the motion monitoring function.

 Figures 3a and 3b illustrate the device of Figure 1
35 mounted in a housing 20. The housing 20 is a lightweight aluminium box or plastics and includes a hook (not shown) on a base 21 of the housing 20, for hooking the housing 20

- 15 -

on to the front of a cage containing an animal patient. Sockets 24 and 25 are provided for receiving respective cables 14 and 26 from the pressure pad 1 and temperature sensor 10, respectively. The loud speaker 4 is also
5 mounted to the housing 20 to enable emission of the audible alarm.

The front panel display 21a (see figure 3a) includes LEDs 3. LED 3a indicates that the device is on charge. LED 3b is a red LED providing visual alarm that the signal
10 from the monitor is passed over the threshold level. LED 3c indicates a low battery.

An LCD 22 is also provided which may provide a display of actual motion rate and temperature. Buttons 6 are also provided, including quick set button 6a (the same
15 baseline rate), on off switch B, etc.

As well as an operator being able to program the alarm settings by way of the switches 6, the microprocessor 9 is programmed with default high and low alarm settings for different animal patients as discussed above. If a
20 rabbit is the patient, for example, the keyboard 23 will be actuated to produce the default settings for a rabbit (by actuating a button which may be a virtual button on a GUI on the LCD display 5). Similarly, for other animal patients.

25 Further, default high and low alarm settings for respiratory rate and temperature are programmed into the microprocessor to suit typical small animal patients recovering from anaesthesia. These settings are automatically enabled, without any action by the operator,
30 on turning on of the monitor. The alarm functions are automatically returned to the default settings if the monitor is powered down, then restarted.

The default settings may, for example, be set at the following:

35

Respiration

High: 25 breaths per minute

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Low: 5 breaths per minute.

Temperature

High: 40°C

Low: 32°C.

5

If an alarm triggers, the monitor is arranged so that the auditory alarm can be turned off by actuating the keypad, but the visual alarm, light 6A, will stay on and the LCD screen 22 back light turns on until the alarm condition has been resolved. The visual alarm enables an operator to rapidly determine from which cage or animal the alarm condition has occurred, even in a dimly lighted recovery room.

Further, as discussed above, the monitor is arranged to have a "quick set" function, which when actuated automatically brackets the alarm settings to the actual parameters of a patient at any point in time. This allows the monitored alarms to be simply and instantly customised to any patient despite the wide variety of patient size and condition encountered in animal veterinary medicine. The quick set thresholds may be set as follows.

	LOW	HIGH
TEMPERATURE	-5%	+10%
MOTION	-20%	+20%

As discussed above, heating devices are often used for animal patients with small body mass, to keep their temperature up as they are recovering from anaesthesia or undergoing critical care. In another embodiment (not shown) the monitor is connected to the power outlet for the heating device and is arranged to automatically shut off the heating device should the temperature rise to the threshold level. Further, it may be arranged to automatically switch on the heating device again when the temperature drops to a predetermined level (note that the predetermined level may not necessarily be the threshold

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level which indicates the onset of hyperthermia, but may be higher).

As well as an alarm, a peripheral device 11, such as a ventilator, for example, may be actuated when the
5 predetermined threshold levels are reached, or when other predetermined threshold levels are reached.

The device may include a radio transmitter (not shown in this embodiment) for sending radio frequency signals to control the power outlet for the heating device or to
10 control the peripheral device, as opposed to being hard - wired.

An alternative embodiment of the device enables analysis of the motion of the patient to determine their medical condition. As discussed in the preamble of this
15 document, an analysis of the motion of a patient who is sedated or in critical care can tell a lot about the condition of the patient. An animal in pain, for example, will either remain totally still, or will move in a rhythmic, "jerky" fashion. This is as opposed to an animal
20 who is not in pain who would probably move in an irregular fashion over a relatively long period of time (e.g., a day). The painful animal is likely to remain immobilised or to move rhythmically for relatively long periods of time. The painless animal would just go about its normal
25 processes, e.g., eating, walking around, lying down, etc. An analysis of motion of a patient over a period of time can therefore provide information about its medical condition. Trend analysis can be carried out of the motion to determine whether the patients condition is, for
30 example, improving or deteriorating.

In one embodiment of the present invention, the device of figure 1 provides an output of the rate of motion either to a display, a printer, or to a personal computer. A physician can study the display or the print out, to use
35 this determine the medical condition of the patient. Alternatively, the PC can be programmed with a program analysing the motion and providing an output which

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indicates what the condition of the patient is at any time, e.g., painful, normal; improving, deteriorating.

Output from the microprocessor 9, depending upon the detected motion may also control a peripheral 11, such as a
5 syringe pump for turning on and off analgesic flow in e.g., painful animals.

Note that the pressure pad 1 could be made the same size as the bottom of an animal cage, for example, to ensure that total motion of the animal is tracked.

10 Figure 5a is a schematic example of a print out over a period of time (say several hours) of motion for an animal which may be healthy. Period X is indicative of a healthy animal asleep; period Y of a healthy animal awake and moving around the cage; period Z of a healthy animal
15 awake and sitting.

On the other hand, figure 5b illustrates the sort of regular motion (e.g., shivering) that may be observed with an animal in pain. This animal does not exhibit normal sleep/wake and activity cycles such as eating.

20 Alternatively, an animal in sever pain may have no body movement at all (conscious but still). So only the regular respiration movement would be observed.

Note that the waveforms 5a and 5b are for illustration only and it may be that the waveforms do not
25 appear like this. The intention here is merely to demonstrate that the motion of a patient tracked over time can provide an indication of their medical condition which can be analysed and used to determine medical treatment.

In the above described embodiments of the invention,
30 a single monitor device, mounted in a housing is used for each animal patient. An alternative embodiment (not shown) receives signals from a plurality of patients to a single monitoring device which includes separate alarms for each patient, but which may include a single display. Such a
35 monitoring device could easily be followed by a single person at a central monitoring station.

The device may be adapted for use with human

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patients.

The device may also be used during surgery.

In a further embodiment, the device may operate independently as a temperature monitor or a motion monitor.

5 Preferably, the microprocessor 9 is aware of whether a temperature sensor or a pressure pad is present. If only one is present, the device will automatically then operate only as a temperature or pressure monitor, whichever device is present.

10 In the above embodiments, the sensor arrangement for monitoring motion is a pressure pad. It would be possible to use other sensor arrangements to monitor motion. For example, infra-red sensors could be placed in the space where the patient is housed (e.g., cage). A further
15 alternative is a video camera.

In a further alternative embodiment, a conventional respiratory motion sensor may be used in conjunction with the pad sensor arrangement described above. Instead of using the pad sensor to monitor all motion (respiratory and
20 bodily) the conventional respiration monitor is used to provide a signal indicative of respiratory motion, and this signal is processed and compared with the signal from the pad motion sensor e.g., by subtraction. The remaining signal from the pad motion sensor is then therefore
25 indicative of bodily motion only of the patient. Referring to Fig. 1, a respiratory thermometer 40 is shown schematically in ghost outline. Respiratory and bodily motion can be tracked separately.

The device may output signals to a computer. The
30 computer may be situated so that a physician may monitor the device signals from their home, for example.

Further, the device itself may include an LCD monitor for displaying a trend waveform when monitoring for the medical condition of the patient.

35 Note that the monitor could be provided with a sensitivity control to control the sensitivity of the pad monitor, to cope with different sizes of patients, e.g.

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animal patients.

The alarm provided by the device may be audible or visual. The alarm may include any means which provides an indication that the patient is being aroused, and may
5 include a visual monitor.

In the above embodiment, the sensor arrangement is a pad monitor. Other types of sensor arrangement may be used instead of a pad monitor, such as infra-red beams, for example.

10 Variations and modifications may be made to the invention as shown in the specific embodiments without departing from the spirit or scope of the invention as broadly described. The present embodiments are, therefore, to be considered in all respects as illustrated and not
15 restrictive.

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THE CLAIMS DEFINING THE INVENTION ARE AS FOLLOWS:

1. A method of monitoring a patient under medical care, comprising the steps of providing a sensor arrangement which is arranged to detect motion of the patient, monitoring the motion of the patient by way of the sensor arrangement, determining whether the motion is indicative of patient arousal, and providing an alarm should the motion be indicative of patient arousal.
2. A method in accordance with claim 1, wherein the sensor arrangement is arranged to be responsive to bodily motion of the patient, and when the motion of the patient increases beyond a predetermined threshold indicative of patient arousal, the alarm is provided.
3. A method in accordance with claim 2, wherein the sensor arrangement is also arranged to monitor the respiratory motion of the patient.
4. A method in accordance with any one of claims 1, 2 or 3, wherein the sensor arrangement includes a pad on which the patient lies, the pad mounting a sensor for monitoring motion of the patient.
5. A method in accordance with any one of the preceding claims, further comprising the step of providing an alarm should the motion of the patient cease to be detected.
6. A method in accordance with claim 5, further comprising the step of providing an alarm should the motion of the patient fall below a predetermined value.
7. A method in accordance with any preceding claim, further comprising the step of monitoring the body temperature of the patient and providing an alarm should the body temperature rise above or below predetermined values.
8. A method in accordance with claim 7, wherein a temperature sensor is provided proximate or within the patient to constantly monitor the temperature.
9. A method in accordance with claim 8, wherein a control means is arranged to receive signals from the sensor arrangement and temperature sensor, and process those signals to provide the alarms.

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10. A method in accordance with claim 9, wherein the control means is provided housed in a single unit.

11. A method in accordance with any preceding claim, wherein the patient is an animal.

5 12. A method in accordance with claim 11, wherein the animal is monitored during recovery from anaesthesia or when under sedation.

13. A method in accordance with any preceding claim, wherein the patient is a human.

10 14. A method in accordance with claim 2, comprising the step of assessing a baseline motion rate which corresponds to the motion rate of the patient at the time the baseline assessment is made, and setting the predetermined threshold at a predetermined rate above the
15 baseline level.

15. A method in accordance with claim 4, comprising the further step of providing a separate respiratory motion arrangement for measuring respiratory motion of the patient, and comparing a signal from the respiratory motion
20 sensor with the signal from the pad sensor, to obtain an indication of bodily motion of the patient.

16. A device for monitoring a patient under medical care, comprising a sensor arrangement which is arranged to detect motion of the patient, and a control means which is
25 arranged to process signals received from the sensor arrangement to determine whether the motion is indicative of patient arousal, and to provide an alarm should the detected motion be indicative of patient arousal.

17. A device in accordance with claim 16, wherein the
30 sensor arrangement is arranged to detect bodily motion of the patient, and the control means is arranged to provide an alarm when the motion of the patient increases beyond a predetermined threshold.

18. A device in accordance with claim 17, wherein the
35 sensor arrangement is also arranged to detect motion due to respiration of a patient.

19. A device in accordance with any one of claims 16 to 18, wherein the sensor arrangement includes a pad on which the patient lies, the pad mounting a sensor for

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monitoring motion of the patient.

20. A device in accordance with any one of claims 16 to 19, wherein the control means is also arranged to process the signals from the motion monitor to determine whether the motion of the patient has ceased and to produce an alarm if the motion of the patient ceases.

21. A device in accordance with claim 20, wherein the device is arranged to provide an alarm should the signal indicate that the motion of the patient has fallen below a predetermined level.

22. A device in accordance with claim 21 including input means enabling the predetermined level to be set.

23. A device in accordance with any one of claims 16 to 22, the control means being automatically arranged to provide default settings for the predetermined level.

24. A device in accordance with any one of claims 16 to 23, including a baseline set means, which when actuated presets a baseline motion rate which corresponds to the motion rate of the patient at the time the baseline set function is actuated, the predetermined level being taken from the baseline level.

25. A device in accordance with any one of claims 16 to 24, wherein the control means is arranged to receive input from a temperature sensor sensing the body temperature of the patient, and is arranged to provide an alarm should the patient's body temperature fall outside predetermined values.

26. A device in accordance with any one of claims 16 to 21, adapted for use with animal patients.

27. A device in accordance with claim 26, wherein the control means and a display for providing visual indication of patient parameters are mounted in a housing which is adapted to be mounted to a cage for containing the animal patient.

28. A device in accordance with any one of claims 16 to 25, wherein the device is adapted for a human patient.

29. A device in accordance with any one of claims 19 to 28, comprising a further sensor arrangement for monitoring respiratory motion of the patient, the control

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means being arranged to compare the signal from the further sensor arrangement and the signal from the sensor arrangement, to give an indication of the bodily motion of the patient.

5 30. A system for monitoring animal patients recovering from anaesthesia, comprising a plurality of devices in accordance with any one of claims 26 to 29, the sensor arrangement being mounted in each case in a cage for retaining an animal recovering from anaesthesia.

10 31. A method of monitoring a patient under medical care, comprising the steps of providing a sensor arrangement which is arranged to detect motion of the patient, monitoring the motion of the patient by way of the sensor arrangement, and analysing the motion of the patient
15 to determine the medical condition of the patient.

 32. A method in accordance with claim 31, wherein the step of analysing the motion of the patient involves tracking the rate of motion over a period of time.

 33. A method in accordance with claim 32, comprising
20 the further step of applying trend analysis to monitor trends in the motion of the patient.

 34. A method in accordance with any one of claims 31, 32 or 33, wherein bodily motion of the patient is monitored.

25 35. A method in accordance with any one of claims 31 to 34, wherein respiratory motion of the patient is monitored.

 36. A method in accordance with any one of claims 31 to 35, wherein the step of analysing the motion of the
30 patient is arranged to determine whether or not the patient is displaying signs of painfulness.

 37. A device for monitoring a patient under medical care, comprising a sensor arrangement which is arranged to detect motion of the patient, and a control means which is
35 arranged to process signals received from the sensor arrangement to analyse the motion of the patient, whereby to enable a determination of the medical condition of the patient.

 38. A device in accordance with claim 37, arranged to

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output a graphical output which indicates the rate of motion over a time period of the patient, which can be used to analyse the medical condition of the patient.

39. A device in accordance with claim 37 or claim 38,
5 the sensor arrangement being arranged to monitor bodily motion of the patient.

40. A device in accordance with any one of claims 37, 38 or 39, wherein the sensor arrangement is arranged to monitor respiratory motion of the patient.

10 41. A device in accordance with any one of claims 37 to 40, wherein the device is arranged to process the signals to analyse the motion of the patient to determine whether or not the patient is displaying signs of painfulness.

15 42. A method in accordance with any one of claims 1 to 15 or 31 to 36, comprising the further step of controlling a peripheral device depending upon the motion of the patient.

20 43. A device in accordance with any one of claims 15 to 29 or 37 to 40, further comprising means for controlling a peripheral device depending upon the motion of the patient.

25 44. A device for monitoring a patient under medical care, the device comprising a control means which is arranged to receive input from a temperature sensor sensing the body temperature of the patient, and is arranged to provide an alarm should the patients body temperature fall above or below predetermined thresholds.

30 45. A device in accordance with claim 44, the control means being arranged to control a peripheral unit depending upon the temperature of the patient.

46. A device in accordance with claim 45, wherein the peripheral unit is a heating device.

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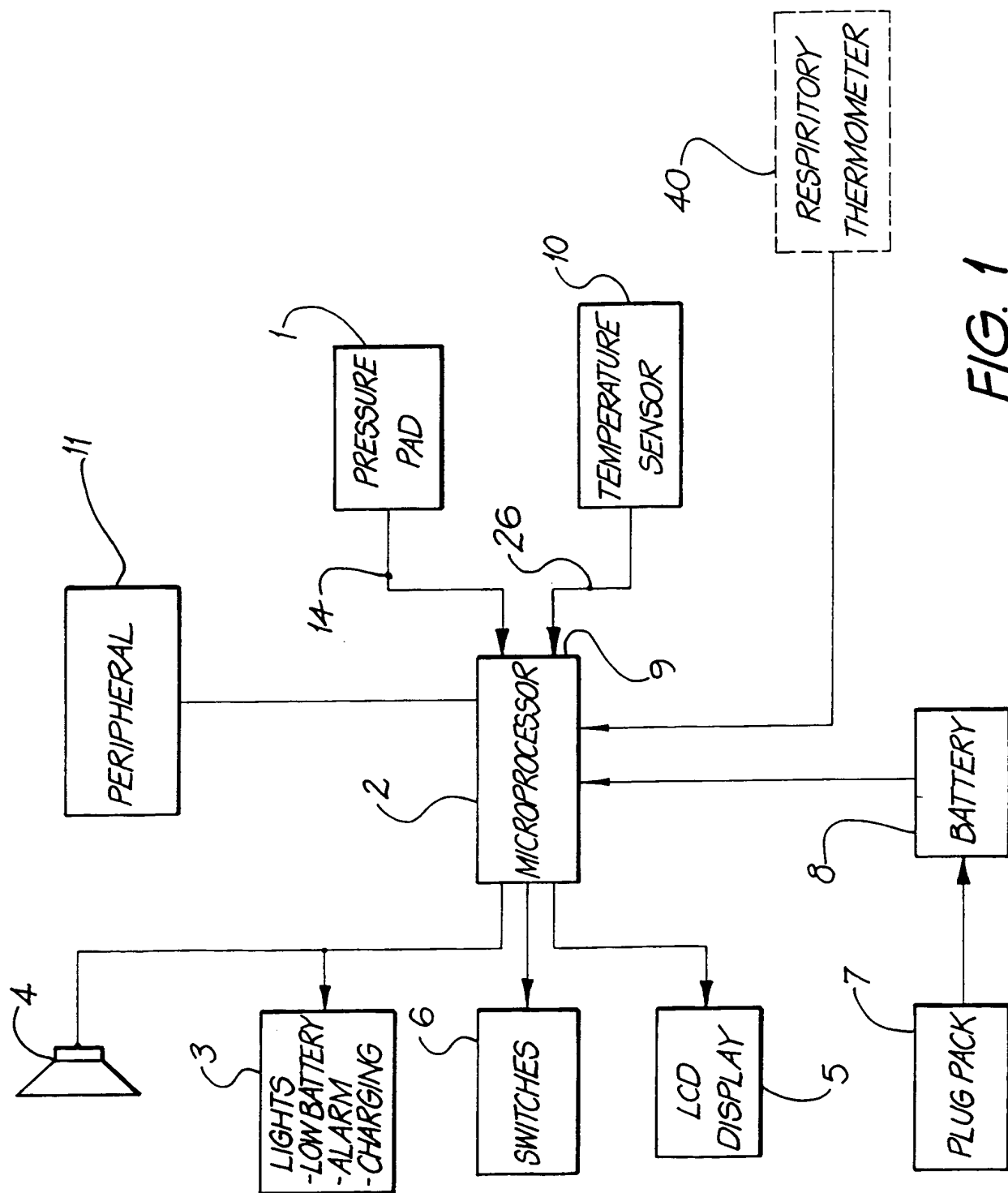


FIG. 1

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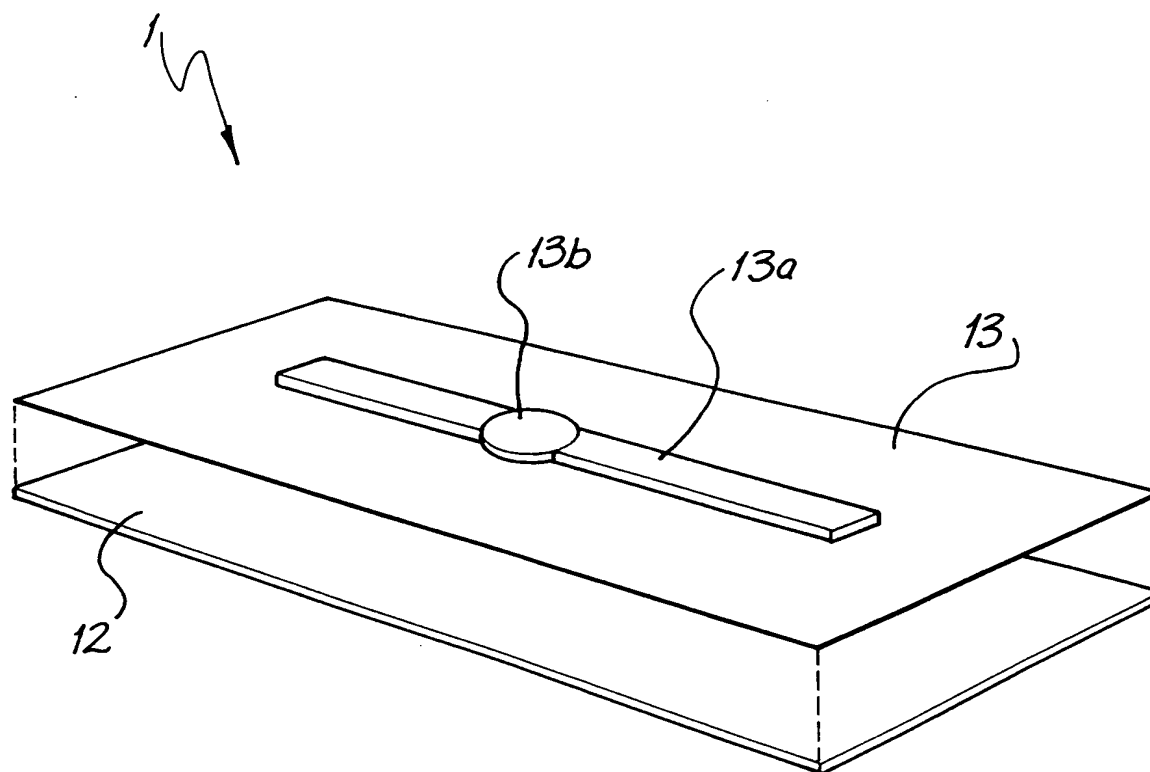


FIG. 2

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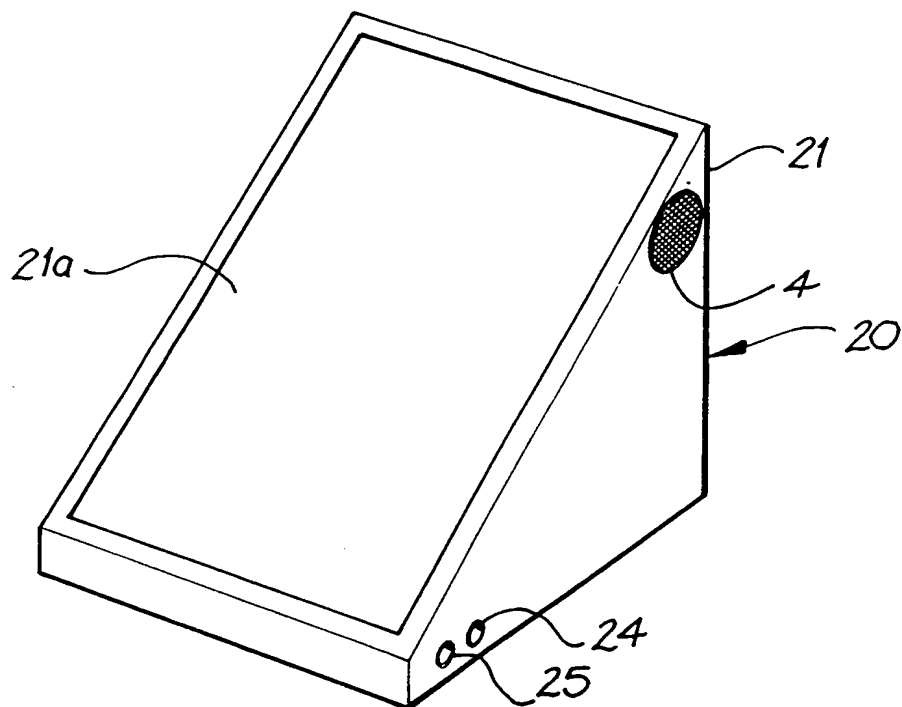
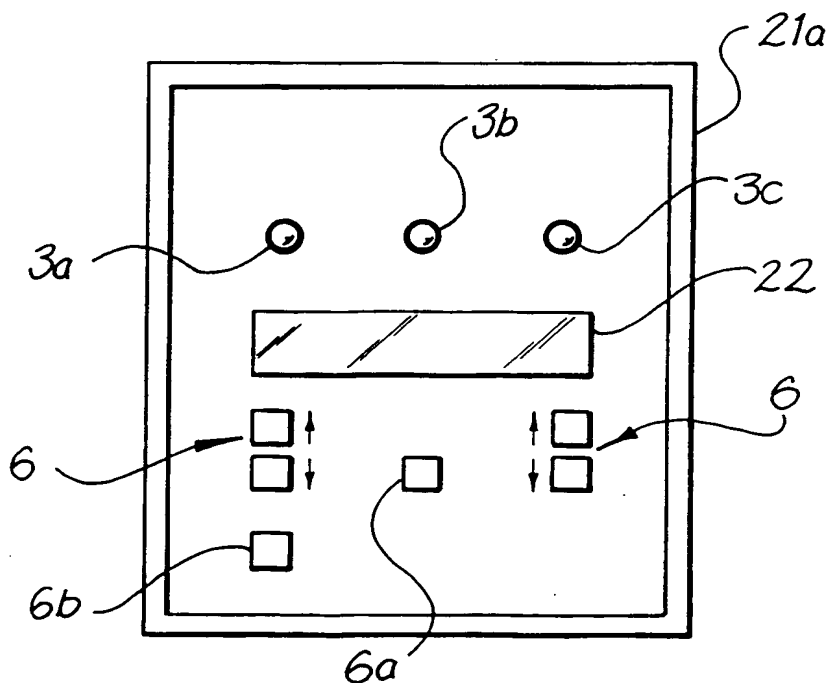


FIG. 3a



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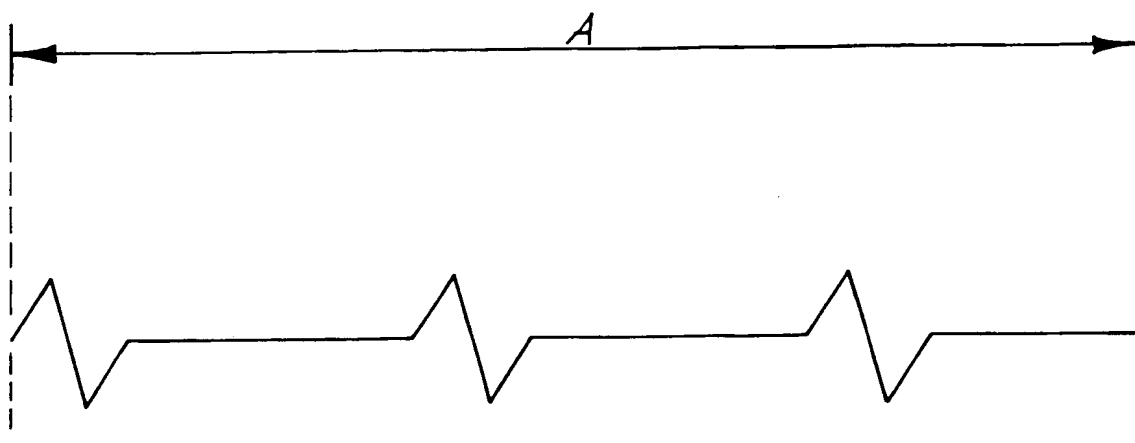


FIG. 4a

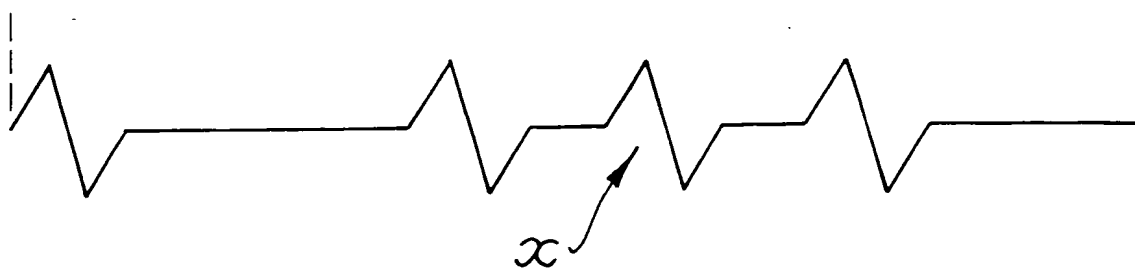
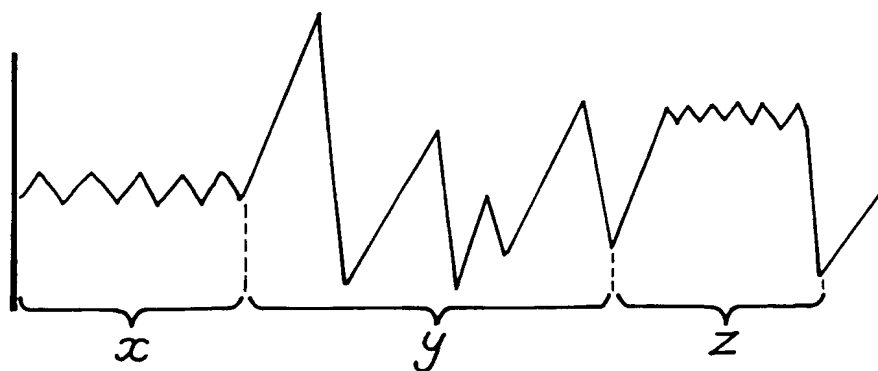
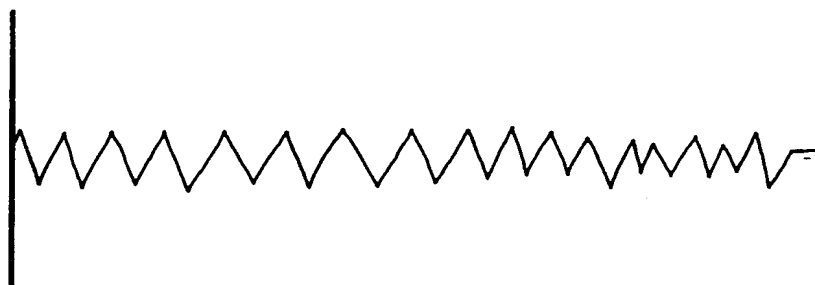


FIG. 4b

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*FIG. 5a**FIG. 5b*

INTERNATIONAL SEARCH REPORT

 International application No.
PCT/AU00/00456
A. CLASSIFICATION OF SUBJECT MATTERInt. Cl. ⁷: A61B 5/11

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC: A61B 5/-, A61D-

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practicable, search terms used)

WPAT + Keywords

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5195531 A (BENNET) 23 March 1993 figure 2 and column 7, lines 19-40	1, 2, 11-13, 16, 17, 26-28, 30, 31, 36-39, 41
X	EP 702978 A2 (MEDTRONIC, INC.) 27 March 1996 column 16, line 51 - column 17, line 28	1-3, 11, 13, 15, 16, 18, 26-29, 31-35, 37- 40, 42, 43
X	US 4836219 A (HOBSON et al.) 6 June 1989 figure 1 and column 4, line 18 - column 5, line 26	1, 2, 11, 13, 16, 17, 26, 28, 31, 37-39

☒ Further documents are listed in the continuation of Box C
 ☒ See patent family annex

* Special categories of cited documents: "A" document defining the general state of the art which is not considered to be of particular relevance "E" earlier application or patent but published on or after the international filing date "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified) "O" document referring to an oral disclosure, use, exhibition or other means "P" document published prior to the international filing date but later than the priority date claimed		"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art "&" document member of the same patent family
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Date of the actual completion of the international search

17 July 2000

Date of mailing of the international search report

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INTERNATIONAL SEARCH REPORT

International application No.
PCT/AU00/00456

C (Continuation). DOCUMENTS CONSIDERED TO BE RELEVANT		
Category*	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	US 5280791 A (LAVIE) 25 January 1994 column 2, line 21 - column 3, line 19	1, 16, 31, 37

INTERNATIONAL SEARCH REPORT

International application No.

PCT/AU00/00456

Supplemental Box

(To be used when the space in any of Boxes I to VIII is not sufficient)

Continuation of Box No: II

The international application does not comply with the requirements of unity of invention because it does not relate to one invention or to a group of inventions so linked as to form a single general inventive concept. In coming to this conclusion the International Searching Authority has found that there are different inventions as follows:

1. Claims 1 to 43 are directed to a method of monitoring a patient under medical care. It is considered that using a sensor to detect motion and then determining whether that motion is indicative of patient arousal comprises a first "special technical feature".
2. Claims 44 to 46 are directed to a device for monitoring a patient under medical care. It is considered that using a sensor to detect temperature and then comparing the measurement with a predetermined threshold comprises a second "special technical feature".

The feature common to all of the claims is the monitoring of a patient under medical care using a sensor. However this common feature is generic in the art. Consequently the common feature does not constitute "a special technical feature" within the meaning of PCT Rule 13.2, second sentence, since it makes no contribution over the prior art. Since there exists no other common feature which can be considered as a special technical feature within the meaning of PCT Rule 13.2, second sentence, no technical relationship within the meaning of PCT Rule 13 between the different inventions can be seen. Consequently it appears that a posteriori, the claims do not satisfy the requirement of unity of invention.

INTERNATIONAL SEARCH REPORT
Information on patent family members

International application No.
PCT/AU00/00456

This Annex lists the known "A" publication level patent family members relating to the patent documents cited in the above-mentioned international search report. The Australian Patent Office is in no way liable for these particulars which are merely given for the purpose of information.

Patent Document Cited in Search Report			Patent Family Member		
US	5195531	NONE			
EP	702978	JP	8224317	US	5522862
US	4836219	NONE			
US	5280791	IL	100080		
END OF ANNEX					